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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,106	07/11/2001	Haile Tecle	5940-01-SMH	7962

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EXAMINER

SHAMEEM, GOLAM M

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ART UNIT                  PAPER NUMBER

1626

DATE MAILED: 09/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/889,106	TECLE ET AL.
	Examiner	Art Unit
	Golam M M Shameem	1626

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 May 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-50 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other:

## **DETAILED ACTION**

Claims 1-50, are pending in this application.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

### ***Lack of Unity Requirement***

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous variables in the claims, e.g. W, R<sub>1</sub>, R<sub>4</sub> and R<sub>5</sub> etc. (and the provisos) and their widely divergent meanings, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I claim(s) 1-29, drawn to a compound of the formula (I) wherein, R<sub>1</sub> is heterocyclic radical (such as pyrrole, pyrazole), R<sub>2</sub> and R<sub>3</sub> is independently H, phenyl, C<sub>1-4</sub> alkyl, C<sub>3-8</sub> alkynyl, C<sub>3-8</sub> cycloalkyl, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> is independently H, CL, F, or Br, R<sub>A</sub> and J are heterocyclic radical (such as pyrrole, pyrazole), R<sub>C</sub>, R<sub>D</sub>, R<sub>E</sub>, R<sub>F</sub> and R<sub>G</sub> is independently selected from pyrrolidinyl and all other variable substitutions are as defined and one method of use (e.g. treating cancer).

Group II claim(s) Group I claim(s) 1-29, drawn to a compound of the formula (I) wherein, R<sub>1</sub> is heterocyclic radical (such as morpholinyl, pyrazinyl), R<sub>2</sub> and R<sub>3</sub> is independently H, phenyl, C<sub>1-4</sub> alkyl, C<sub>3-8</sub> alkynyl, C<sub>3-8</sub> cycloalkyl, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> is independently H, CL, F, or Br, R<sub>A</sub> and J are heterocyclic radical (such as morpholinyl, pyrazinyl), R<sub>C</sub>, R<sub>D</sub>, R<sub>E</sub>, R<sub>F</sub> and R<sub>G</sub> is independently selected from pyrazinyl and all other variable substitutions are as defined and one method of use (e.g. treating septic shock).

Group III Group I claim(s) 1-29, drawn to a compound of the formula (I) wherein, R<sub>1</sub> is non-heterocyclic radical (such as H, C <sub>1-8</sub> ayl, C <sub>3-8</sub> alkenyl, C <sub>3-8</sub> alkynyl, phenyl, C <sub>3-8</sub> cycloalkyl etc.), R<sub>2</sub> and R<sub>3</sub> is independently H, phenyl, C <sub>1-4</sub> alkyl, C <sub>3-8</sub> alkynyl, C <sub>3-8</sub> cycloalkyl, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> is independently H, CL, F, or Br, R<sub>A</sub> and J are non-heterocyclic radical (such as H, C <sub>1-6</sub> ayl, C <sub>3-8</sub> alkenyl, C <sub>3-8</sub> alkynyl, phenyl, C <sub>3-8</sub> cycloalkyl etc.), R<sub>C</sub>, R<sub>D</sub>, R<sub>E</sub>, R<sub>F</sub> and R<sub>G</sub> is independently selected from non-heterocyclic radical (such as H, C <sub>1-6</sub> ayl, C <sub>3-8</sub> alkenyl, C <sub>3-8</sub> alkynyl, phenyl, C <sub>3-8</sub> cycloalkyl etc.) and all other variable substitutions are as defined and one method of use (e.g. treating cystic fibrosis).

Group IV claims 30-48, drawn to a method for treating a disease with the compound of the formula (I) wherein, R<sub>1</sub> is heterocyclic radical (such as pyrrole, pyrazole), R<sub>2</sub> and R<sub>3</sub> is independently H, phenyl, C <sub>1-4</sub> alkyl, C <sub>3-8</sub> alkynyl, C <sub>3-8</sub> cycloalkyl, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> is independently H, CL, F, or Br, R<sub>A</sub> and J are heterocyclic radical (such as pyrrole, pyrazole), R<sub>C</sub>, R<sub>D</sub>, R<sub>E</sub>, R<sub>F</sub> and R<sub>G</sub> is independently selected from pyrrolidinyl and all other variable substitutions are as defined heterocyclic radical and all other variable substitutions are as defined.

Group V claims 30-48, drawn to a method for treating a disease with the compound of the formula (I) wherein, R<sub>1</sub> is heterocyclic radical (such as morpholinyl, pyrazinyl), R<sub>2</sub> and R<sub>3</sub> is independently H, phenyl, C <sub>1-4</sub> alkyl, C <sub>3-8</sub> alkynyl, C <sub>3-8</sub> cycloalkyl, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> is independently H, CL, F, or Br, R<sub>A</sub> and J are heterocyclic radical (such as morpholinyl, pyrazinyl), R<sub>C</sub>, R<sub>D</sub>, R<sub>E</sub>, R<sub>F</sub> and R<sub>G</sub> is independently selected from pyrazinyl and all other variable substitutions are as defined.

Group VI Group I claim(s) 30-48, drawn to a compound of the formula (I) wherein, R<sub>1</sub> is non-heterocyclic radical (such as H, C <sub>1-8</sub> ayl, C <sub>3-8</sub> alkenyl, C <sub>3-8</sub> alkynyl, phenyl, C <sub>3-8</sub>

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cycloalkyl etc.), R<sub>2</sub> and R<sub>3</sub> is independently H, phenyl, C<sub>1-4</sub> alkyl, C<sub>3-8</sub> alkynyl, C<sub>3-8</sub> cycloalkyl, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> is independently H, CL, F, or Br, R<sub>A</sub> and J are non-heterocyclic radical (such as H, C<sub>1-6</sub> ayl, C<sub>3-8</sub> alkenyl, C<sub>3-8</sub> alkynyl, phenyl, C<sub>3-8</sub> cycloalkyl etc.), R<sub>C</sub>, R<sub>D</sub>, R<sub>E</sub>, R<sub>F</sub> and R<sub>G</sub> is independently selected from non-heterocyclic radical (such as H, C<sub>1-6</sub> ayl, C<sub>3-8</sub> alkenyl, C<sub>3-8</sub> alkynyl, phenyl, C<sub>3-8</sub> cycloalkyl etc.) and all other variable substitutions are as defined.

Group VII claims 49-50, drawn to a method for treating a disease with chemotherapy using the compound of the formula (I) wherein, R<sub>1</sub> is heterocyclic radical (such as pyrrole, pyrazole), R<sub>2</sub> and R<sub>3</sub> is independently H, phenyl, C<sub>1-4</sub> alkyl, C<sub>3-8</sub> alkynyl, C<sub>3-8</sub> cycloalkyl, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> is independently H, CL, F, or Br, R<sub>A</sub> and J are heterocyclic radical (such as pyrrole, pyrazole), R<sub>C</sub>, R<sub>D</sub>, R<sub>E</sub>, R<sub>F</sub> and R<sub>G</sub> is independently selected from pyrrolidinyl and all other variable substitutions are as defined.

Group VIII claims 49-50, drawn to a method for treating a disease with chemotherapy using the compound of the formula (I) wherein, R<sub>1</sub> is heterocyclic radical (such as morpholinyl, pyrazinyl), R<sub>2</sub> and R<sub>3</sub> is independently H, phenyl, C<sub>1-4</sub> alkyl, C<sub>3-8</sub> alkynyl, C<sub>3-8</sub> cycloalkyl, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> is independently H, CL, F, or Br, R<sub>A</sub> and J are heterocyclic radical (such as morpholinyl, pyrazinyl), R<sub>C</sub>, R<sub>D</sub>, R<sub>E</sub>, R<sub>F</sub> and R<sub>G</sub> is independently selected from pyrazinyl and all other variable substitutions are as defined.

Group IX claims 49-50, drawn to a method for treating a disease with chemotherapy using the compound of the formula (I) wherein, R<sub>1</sub> is non-heterocyclic radical (such as H, C<sub>1-8</sub> ayl, C<sub>3-8</sub> alkenyl, C<sub>3-8</sub> alkynyl, phenyl, C<sub>3-8</sub> cycloalkyl etc.), R<sub>2</sub> and R<sub>3</sub> is independently H, phenyl, C<sub>1-4</sub> alkyl, C<sub>3-8</sub> alkynyl, C<sub>3-8</sub> cycloalkyl, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> is independently H, CL, F, or Br, R<sub>A</sub> and J are non-heterocyclic radical (such as H, C<sub>1-6</sub> ayl, C<sub>3-8</sub> alkenyl, C<sub>3-8</sub> alkynyl, phenyl, C

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$C_{3-8}$  cycloalkyl etc.),  $R_C$ ,  $R_D$ ,  $R_E$ ,  $R_F$  and  $R_G$  is independently selected from non-heterocyclic radical (such as H,  $C_{1-6}$  ayl,  $C_{3-8}$  alkenyl,  $C_{3-8}$  alkynyl, phenyl,  $C_{3-8}$  cycloalkyl etc.) and all other variable substitutions are as defined.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhausted, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same. If applicant wishes to elect subject matter other than that identified in the above groups, applicant may elect a species and examiner will attempt to group it. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a heterocyclic or non-heterocyclic radical substitution, which is attached to core benzene ring that does not define a contribution over the prior art. The substituents on the benzene ring vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, the numerous provisos found in the claims, and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

*Conclusion*

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is 703-305-0116. The examiner can normally be reached on 6:30 AM to 5:00 PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 703-308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7921 for regular communications and 703-308-7921 for after final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A facsimile center has been established. The hours of operation are Monday through 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.

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September 26, 2002

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